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09/699744
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PATENT APPLICATION TRANSMITTAL FORM

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KENNETH R. SCHAEFER, ESQ.
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(Signature of person mailing paper or fee)

Transmitted herewith for filing is the patent application of

Inventor(s): GLICK, FRANCINE & PUCHALSKI, JR., EUGENE

For: ANTIBACTERIAL COMPOSITIONS AND METHOD OF USING SAME

Enclosed are:

- X Specification and Claims with Declaration; 19 PAGES
- ☐ Specification and Claims without Declaration;
- _____ sheets of informal drawings and 2 sets of copies thereof;
- ☐ _____ sheets of formal drawings and 2 sets of copies thereof;
- ☐ An assignment of the invention to _____;
- ☐ The certified copy of a priority application;
- ☐ Information Disclosure Statement;
- ☐ Copies of citations as listed on attached _____ form;
- ☐ Address all future communications to: Kenneth R. Schaefer, Esq., 25 Dickinson Road, Basking Ridge, NJ 07920

☐X Small Entity Status Claimed

☐X Priority of Provisional application Serial No. 60/163,982 filed on November 8, 1999 is claimed.

☐X The Filing Fee is calculated below.

CLAIMS AS FILED				
	(1) For	(2) Number Filed	(3) Number Extra	(4) Rate	(5) Basic Fee $710
	Total Claims	12 - 20 =0	0	x .00	$000
	Independent Claims	2 - 3 =0	0	x .00	$000
	Multiple Dependent Claim Fee		0	$ .00	$000
	☐X Fee reduced by 50%.*			TOTAL FILING FEE	$355.00

☐X A check in the amount of $ 355.00 to cover the filing fee is attached.

10/30/00
Date of Signature

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ANTIBACTERIAL COMPOSITIONS AND METHOD OF USING SAME

RELATED APPLICATIONS

This application claims the benefit of the filing date of U. S. Provisional Application Serial No. 60/163,982, filed November 8, 1999.

FIELD OF THE INVENTION

This invention relates to antibacterial solutions useful as a cleansing agent suitable for cutaneous use by humans, as well as for application to non-absorbent equipment surfaces. The solution is designed to be applied directly to the surface which is to be cleaned without any need to rinse it off. The antimicrobial solution is aqueous based, is free of surfactants, alcohol or other skin-drying or odor producing ingredients and contains a quaternary ammonium compound as its principal antimicrobial agent. The solution also contains a combination of moisturizing agents such as extracts of aloe vera, lavender and chamomile. Additionally, DMDM hydantoin is blended into the solution and acts at least as a preservative.

BACKGROUND

There are a large number of formulations for antibacterial cleansing solutions which include the quaternary ammonium compound Benzalkonium Chloride. At least some of the benzalkonium chloride formulations also make use of DMDM Hydantoin (e.g. "Glydant XL1000") as a preservative in the solution(see for example, U.S. Patent No. 5,914,300, granted June 22 1999 in the names of Fujiwara et al., which is assigned to Lever Brothers Company).

Although the antibacterial effect of benzalkonium chloride has been recognized by

workers in this field, nevertheless, it is customary to include materials in the cleaning solution such as surfactants and/or alcohols to provide a significant degree of the desired cleansing and antibacterial effects. In addition, in most instances, fragrances are added to the composition as well to provide supposedly desirable characteristics to the product.

It has been found, however, that a highly effective and desirable antibacterial cleansing solution which does not require rinsing preferably is formulated free of fragrance, alcohol and surfactants. The undesirable drying effect of alcohol on the skin is avoided while, at the same time, providing an aqueous-based, substantially residue-free, odor-free, effective antibacterial cleansing solution. The solution may be applied as a spray or liquid or it may be saturated in a medium such as an absorbent gauze or other fabric (e.g. a towelette) which is used as a "wipe" on the skin or surface to be cleaned.

An exemplary formulation includes a water phase, a principal active phase, a preservative phase which also exhibits antibacterial effects and a moisturizing phase.

STATEMENT OF INVENTION

It is an object of the present invention to provide a novel, effective anti-bacterial cleansing solution containing only ingredients which are specifically selected as non-irritating, non-drying and beneficial to the skin. At the same time, it has been found that such a cleansing solution can be formulated so as to be an effective anti-bacterial cleanser for non-porous equipment and other surfaces such as may be encountered in environments such as medical treatment, food handling or otherwise, where the presence of bacteria would be a concern.

With these objectives in mind, an effective anti-bacterial cleaning solution has been developed which is alcohol-free, surfactant-free and odor-free and comprises a quaternary ammonium compound in aqueous solution as its principal antimicrobial agent. The solution also contains a combination of moisturizing agents such as extracts of aloe vera, lavender

and chamomile. Additionally, DMDM hydantoin is blended into the solution and acts at least as a preservative.

Certain preservatives known to be useful in liquid skin cleansers have been described as effective as preservatives because they exhibit antibacterial (and antifungal) effects themselves. It is believed that the preservative DMDM Hydantoin is one such preservative which not only provides an antibacterial effect itself but, under appropriate conditions, enhances the antibacterial effect of the principal antibacterial agent, benzalkonium chloride, when the two are combined in aqueous solution as described herein.

The principal antibacterial agent (benzalkonium chloride) can be present at a level of from about 0.1% to about 5% by weight, typically from about 0.5% to about 1.5%. The level is selected to provide the desired level of antibacterial activity and can be modified within the indicated ranges as desired.

The stated moisturizing agents (extracts of aloe vera, chamomile and lavender) can be present at a level of about 0.1% to about 5% by weight as a group. The principal preservative compound (DMDM Hydantoin) can be present at a level of about 0.1% to about 2% by weight. The remainder of the solution is made up of sterile water.

As a general proposition, a suitable antibacterial cleansing solution should be stable and should not deteriorate over a period of time under normal anticipated storage conditions. Further desirable attributes are that the solution should be relatively free of constituents which sensitize or irritate human skin. While a large percentage of the solution constituents are relatively inactive or inert, and serve mainly to carry or permit spreading the active ingredients, it is desirable that appropriate moisturizing or hydrating ingredients be present in order to facilitate penetration of the solution, at least to some extent, into the upper skin layer. To that end, the indicated moisturizing agents are included.

While the invention will be described in connection with a particular preferred embodiment as set forth hereinafter, it should be recognized that various modifications as may be apparent to persons skilled in the art also may be made without departing from the

invention.

DETAILED DESCRIPTION

In its principal application, the inventive formulation is intended to be applied either directly or indirectly to the skin. Where a spray applicator is used, the solution is sprayed onto each hand (or skin surface which is to be cleansed) and thereafter the skin is hand rubbed gently until it is dry. Where a towelette soaked with the anti-bacterial solution is employed, the towelette is rubbed over the surface to be cleansed and transfers the solution to the surface, where it is allowed to dry in situ. The presence of the moisturizing agents, along with the absence of other objectionable residues or odors, leaves the skin clean, disinfected and pleasing to the touch.

The cleansing solution according to the present invention has been tested on humans and has been found to be non-irritating and effective as desired. The results of tests are set forth below.

IRRITATION AND SENSITIZATION TESTS

Fifty-five subjects, male and female, ranging in age from 18 to 76 years, were selected for this evaluation. Fifty subjects completed this study. The remaining subjects discontinued their participation for various reasons unrelated to the study or the material tested. The subjects were selected on the basis, among other things, of the absence of any visible skin disease which might be confused with skin reactions from the test material, as well as avoidance of use of topical or systemic steroids and/or antihistamines for several days prior to study initiation.

The upper back between the scapulae served as the test area. Prior to the initiation of this study, towelette material was cut into 1" x 3/4" pieces. These samples were then

placed over the gauze portion of an adhesive dressing and moistened with approximately 0.2 ml of test solution. When applied to the test site, this patch formed a semi-occlusive patch.

This procedure was followed three times per week: Monday, Wednesday and Friday, for a total of ten applications. If a participant was unable to report for an assigned test day, one makeup day was permitted. The test site was marked to ensure the continuity of patch application. Participants were instructed to remove the patch after 24 hours. The site was evaluated just prior to reapplication.

If a test site exhibited a moderate (2+) reaction (see below for key) during the Induction Phase, application would be moved to an adjacent area. Applications would be discontinued for the remainder of this test phase, if a moderate (2+) reaction was observed on this new test site. Applications would also be discontinued if a marked (3+) reaction was noted.

Rest periods consisted of twenty-four hours following each Tuesday and Thursday removal, and forty-eight hours following each Saturday removal. At the conclusion of a rest period of approximately fourteen days following the tenth application, a challenge patch was applied to the original site and to a virgin site. These sites were evaluated at twenty-four and forty-eight hours after application. The volar forearm served as the virgin test site.

EVALUATION KEY

0 - No visible reaction

1+ - Mild erythema

2+ - Well-defined erythema

3+ - Erythema and edema

4+ - Erythema and edema with vesiculation and ulceration

INDIVIDUAL TEST RESULTS

.....INDUCTION PHASE.....

Su No	1	2	3	4	5	6	7	8	9	10		Original Site 24	Original Site 48	Virgin Site 24	Virgin Site 48
1	0	0	0	0	0	0	0	0	0	0		0	0	0	0
2	0	0	0	0	0	0	0	0	0	0		0	0	0	0
3	0	0	0	T*	DID NOT COMPLETE STUDY										
4	0	0	0	0	0	0	0	0	0	0		0	0	0	0
5	0	0	0	0	0	0	0	0	0	0		0	0	0	0
6	0	0	0	0	0	0	0	0	0	0		0	0	0	0
7	0	0	0	0	0	0	0	0	0	0		0	0	0	0
8	0	0	0	0	0	0	0	0	0	0		0	0	0	0
9	0	0	0	0	0	0	0	0	0	0		0	0	0	0
10	0	0	0	0	0	0	0	0	0	0		0	0	0	0
11	0	0	0	0	0	0	0	0	0	0		0	0	0	0
12	0	0	0	0	0	0	0	0	0	0		0	0	0	0
13	0	0	0	0	0	0	0	0	0	0		0	0	0	0
14	DID NOT COMPLETE STUDY														
15	0	0	0	0	0	0	0	0	0	0		0	0	0	0
16	0	0	0	0	0	0	0	0	0	0		0	0	0	0
17	0	0	0	0	0	0	0	0	0	0		0	0	0	0
18	0	0	0	0	0	0	0	0	0	0		0	0	0	0

19	0	0	0	0	0	0	0	0	0	0		0	0	0	0
20	0	0	0	0	0	0	0	0	0	0		0	0	0	0
21	0	0	0	0	0	0	0	0	0	0		0	0	0	0
22	0	0	0	0	0	0	0	0	0	0		0	0	0	0
23	0	0	0	0	0	0	0	0	0	0		0	0	0	0
24	0	0	0	0	0	0	0	0	0	0		0	0	0	0
25	0	0	0	0	0	0	0	0	0	0		0	0	0	0
26	0	0	0	0	0	0	0	0	0	0		0	0	0	0
27	0	0	0	0	0	0	0	0	0	0		0	0	0	0
28	0	0	0	0	0	0	0	0	0	0		0	0	0	0
29	0	0	0	0	0	0	0	0	0	0		0	0	0	0
30	0	0	0	0	0	0	0	0	0	0		0	0	0	0
31	0	0	0	0	0	0	0	0	0	0		0	0	0	0
32	0	0	0	0	0	0	0	0	0	0		0	0	0	0
33	0	0	0	0	0	0	0	0	0	0		0	0	0	0
34	0	0	0	0	0	0	0	0	0	0		0	0	0	0
35	0	0	0	0	0	0	0	0	0	0		0	0	0	0
36	0	0	0	0	0	0	0	0	0 m	0		0	0	0	0
37	0	0	0	0	0	0	0 m	0	0	0		0	0	0	0
38	0	DID NOT COMPLETE STUDY													
39	0	0	0	0	0	0	0	0	0	0		0	0	0	0
40	0	DID NOT COMPLETE STUDY													

41	0	0	0	0	0	0	0	0	0	0		0	0	0	0
42	0	0	0	0	0	0	0	0	0	0		0	0	0	0
43	0	DID NOT COMPLETE STUDY													
44	0	0	0	0	0	0	0	0	0	0		0	0	0	0
45	0	0	0	0	0	0	0	0	0	0		0	0	0	0
46	0	0	0	0	0	0	0	0	0	0		0	0	0	0
47	0	0	0	0	0	0	0	0	0	0		0	0	0	0
48	0	0	0	0	0	0	0	0	0	0		0	0	0	0
49	0	0	0	0	0	0	0	0	0	0		0	0	0	0
50	0	0	0	0	0	0	0	0	0	0		0	0	0	0
51	0	0	0	0	0	0	0	0	0	0		0	0	0	0
52	0	0	0	0	0	0	0	0	0	0		0	0	0	0
53	0	0	0	0	0	0	0	0	0	0		0	0	0	0
54	0	0	0	0	0	0	0	0	0	0		0	0	0	0
55	0	0	0	0	0	0	0	0	0	0		0	0	0	0
T= TAPE REACTION															
m= ADDITIONAL MAKEUP FOR MEDICAL EMERGENCY															

SUBJECT DATA

SUBJECT NUMBER	INITIALS	AGE	SEX
1	LA	74	F
2	JS	24	F
3	JM	28	M
4	MB	67	F
5	AZ	76	M
6	JC	67	F
7	RS	64	M
8	ST	74	F
9	CS	56	F
10	SC	54	F
11	CY	75	M
12	DR	33	F
13	MH	60	F
14	AS	70	F
15	AM	65	F
16	JM	70	M
17	GR	21	F

18	CB	49	F
19	SS	62	F
20	SS	72	M
21	MS	66	F
22	AP	29	F
23	TP	73	M
24	RL	50	F
25	RS	49	M
26	WW	36	M
27	SM	32	F
28	MS	60	F
29	LC	27	F
30	CL	65	F
31	GF	65	F
32	RG	46	M
33	CR	40	F
34	MS	34	F
35	AH	38	F
36	IB	51	F
37	DH	30	F
38	AC	19	F
39	TR	18	F
40	CS	18	M
41	GA	55	F

42	PM	53	F
43	DM	26	F
44	MF	50	F
45	EL	50	F
46	JT	30	F
47	AN	74	F
48	LS	30	F
49	DS	28	M
50	PP	66	M
51	MM	41	F
52	CA	20	F
53	HV	65	F
54	GV	70	M
55	AS	36	M

The results of the tests show negative results (no irritation or other effects) throughout the test intervals. Under the conditions of these studies, the towelette solution/material did not indicate any potential for dermal irritation and/or sensitization.

A sample of solution was submitted for microbiological evaluation and standard time kill test at 30 seconds, 1 minute and 2 minutes.

A "Time Kill Study" was conducted to determine the antibacterial activity of the sample solution after 30 seconds, 1 minute and 2 minutes contact time against Pseudomonas aeruginosa ATCC 15422, S.aureus ATCC 6538 and E.coli ATCC 8739. Results showed

that the sample solution reduced bacteria count by 99.99% at 30 seconds contact time. It is typical for antimicrobial soap products to show a minimum of 99.99% reduction of the test organisms to substantiate antimicrobial claims.

SAMPLE	CONTACT TIME	INITIAL CONCENT. IN SAMPLE	CFU'S/ML OF TEST ORG. AT T=SEC.	PERCENT REDUCTION	
P.aerugino-sa ATTC 15442	30 Sec.	2.7×10^7	Less than 10	99.99%	
	1 Min.	2.7×10^7	Less than 10	99.99%	
	2 Min.	2.7×10^7			
S.aureus ATCC 6538	30 Sec.	2.5×10^7	Less than 10	99.99%	
	1 Min.	2.5×10^7	Less than 10	99.99%	
	2 Min.	2.5×10^7	Less than 10	99.99%	
E.coli ATCC 8739	30 Sec.	4.7×10^7	Less than 10	99.99%	
	1 Min.	4.7×10^7	Less than 10	99.99%	
	2 Min.	4.7×10^7	Less than 10	99.99%	

The use of natural extracts in a water-based solution , which is fragrance, alcohol and surfactant-free, provides a desired moisturizing effect, along with the necessary antibacterial effect and the cleansing solution does not strip the skin of its natural oils.

While the invention has been described in terms of a preferred embodiment and preferred methods of use, it should be recognized that various modifications may be made within the scope of the invention which is pointed out in the following claims.

WHAT IS CLAIMED IS:

1. An alcohol-free, surfactant-free and fragrance-free antibacterial composition comprising:

(1) from about 0.1 to about 5 weight percent benzalkonium chloride;

(2) from about 0.1 to about 2 weight percent DMDM Hydantoin;

(3) from about 0.1 to about 5 total weight percent moisturizing agents distributed among extracts of aloe vera, lavender and chamomile; and

(4) the balance consisting of sterile water.

2. The antibacterial composition of Claim 1 wherein:

said benzalkonium chloride is present in an amount of from about 0.5 to about 1.5 weight percent of said composition.

3. The antibacterial composition according to Claim 1 wherein:

said moisturizing agents are present in an amount from about 0.1 to about 5 weight percent of said composition as a group.

4. The antibacterial composition according to Claim 1 wherein:

said benzalkonium chloride acts as an antibacterial agent in said composition.

5. The antibacterial composition according to Claim 1 wherein:

said benzalkonium chloride acts as the antibacterial agent in said composition.

6. A method of cleansing an area of skin comprising:

applying to the area of skin to be cleansed an alcohol-free and surfactant-free antibacterial composition comprising:

benzalkonium chloride, as an antibacterial agent, present in an amount of from about 0.1 to about 5 weight percent of said composition,

DMDM Hydantoin, present in an amount from about 0.1 to about 2 weight percent of said composition,

moisturizing agents, selected from the group consisting of extracts of aloe vera, lavender and chamomile, present in an amount from about 0.1 to about 5 weight percent of said composition as a group, and

the balance of said composition consisting of sterile water.

7. The method of Claim 6 wherein the composition is applied to the skin of a human.

8. The method of Claim 6 wherein:

the benzalkonium chloride is present in an amount from about 0.5 to about 1.5 weight percent of the solution.

9. The method of Claim 8 wherein:

the step of applying comprises spraying said antibacterial solution on the area to be cleaned.

10. The method of Claim 7 wherein:

the step of applying comprises spraying said antibacterial solution on the area to be cleaned.

11. The method of Claim 8 wherein:

the step of applying comprises wetting a clean cloth with the antibacterial solution and wiping said wet, clean cloth over said area.

12. The method according to Claim 7 wherein:

the step of applying comprises wetting a clean cloth with the antibacterial solution and wiping said wet, clean cloth over said area

ABSTRACT OF THE DISCLOSURE

Antibacterial solution useful as a cleaning agent suitable for cutaneous use by humans or otherwise which is aqueous based, free of alcohol and surfactants and having a quaternary ammonium compound as its principal antimicrobial agent, a number of moisturizing agents and DMDM Hydantoin serving at least as a preservative.

DECLARATION
AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below at 201 et seq. underneath my name.

I believe I am the original, first and sole inventor if only one name is listed at 201 below, or an orginal, first and joint inventor if plural names are listed at 201 et seq. below, of the subject matter which is claimed and for which a patent is sought on the invention entitled

ANTIBACTERIAL COMPOSITIONS AND METHOD OF USING SAME

the specification of which:

X is attached hereto.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119/§172 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

EARLIEST FOREIGN APPLICATION(S), IF ANY, FILED PRIOR TO THE FILING DATE OF THE APPLICATION			
APPLICATION NUMBER	COUNTRY	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER U.S.C. 119/172
			Yes ___ No ___
			Yes ___ No ___
			Yes ___ No ___

I hereby claim the benefit under Title 35, United States Code, 119(e) of any United States provisional application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION SERIAL NUMBER	FILING DATE	STATUS		
		PATENTED	PENDING	ABANDONED
60/163,982	Nov. 8, 1999		X	

POWER OF ATTORNEY: As a named inventor, I hereby appoint Kenneth R. Schaefer, Esq. (Reg. No. 20409), whose address is 25 Dickinson Road, Basking Ridge, New Jersey 07920, my attorney, to prosecute this application, and to transact all business in the Patent and Trademark Office connected therewith, and to file, prosecute and maintain corresponding patent applications and patents in other countries and regional authority offices outside the United States.

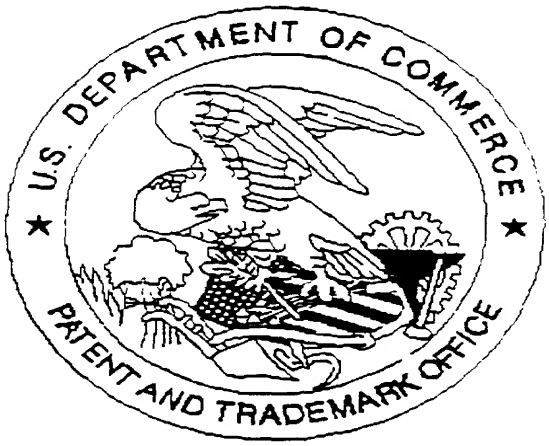
		SEND CORRESPONDENCE TO: **KENNETH R. SCHAEFER, ESQ.** 25 DICKINSON ROAD BASKING RIDGE, NEW JERSEY 07920	**DIRECT TELEPHONE CALLS TO:** KENNETH R SCHAEFER (908) 507 - 8759	
2	FULL NAME OF INVENTOR	LAST NAME GLICK	FIRST NAME FRANCINE	MIDDLE NAME
0	RESIDENCE & CITIZENSHIP	CITY LIVINGSTON	STATE OR FOREIGN COUNTRY NEW JERSEY	COUNTRY OF CITIZENSHIP USA
1	POST OFFICE ADDRESS	POST OFFICE ADDRESS 75 SHREWSBURY DRIVE	CITY LIVINGSTON	STATE OR COUNTRY ZIP CODE NEW JERSEY 07039
2	FULL NAME OF INVENTOR	LAST NAME PUCHALSKI, JR.	FIRST NAME EUGENE	MIDDLE NAME
0	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY NEW JERSEY	COUNTRY OF CITIZENSHIP USA
2	POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE OR COUNTRY ZIP CODE NEW JERSEY

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR **201** Francine Glick	SIGNATURE OF INVENTOR **202**	SIGNATURE OF INVENTOR **203**
DATE 10/29/08	DATE	DATE
SIGNATURE OF INVENTOR **204**	SIGNATURE OF INVENTOR **205**	
DATE	DATE	

United States Patent & Trademark Office

Office of Initial Patent Examination -- Scanning Division



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